Complete Summary

GUIDELINE TITLE

Clinical practice guideline: cerumen impaction.

BIBLIOGRAPHIC SOURCE(S)

Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, Fayad J, Harlor AD Jr, Hirsch BE, Jones SS, Krouse HJ, Magit A, Nelson C, Stutz DR, Wetmore S. Clinical practice guideline: cerumen impaction. Otolaryngol Head Neck Surg 2008 Sep;139(3 Suppl 2):S1-21. [97 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Cerumen impaction, defined as an accumulation of cerumen (earwax) that causes symptoms, prevents assessment of the ear, or both

Note: Cerumen impaction does not require a complete obstruction.

GUIDELINE CATEGORY

Counseling
Diagnosis
Management

Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Nursing
Otolaryngology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To help clinicians identify patients with cerumen impaction who may benefit from intervention, and to promote evidence-based management
- To highlight needs and management options in special populations or in patients who have modifying factors
- To create a guideline suitable for deriving a performance measure on cerumen impaction

TARGET POPULATION

Patients over six months of age with a clinical diagnosis of cerumen impaction:

- *Cerumen* is defined as a mixture of secretions (sebum together with secretions from modified apocrine sweat glands) and sloughed epithelial cells, and is a normal substance present in the external auditory canal. As cerumen migrates laterally, it may mix with hair and other particulate matter.
- *Cerumen impaction* is defined as an accumulation of cerumen that causes symptoms, prevents a needed assessment of the ear canal/tympanic membrane or audiovestibular system, or both.
- *Impaction vs obstruction*: Although "impaction" usually implies that cerumen is lodged, wedged, or firmly packed in the ear canal, our definition of cerumen impaction does not require a complete obstruction.

Note: The guideline does *not* apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; previous tympanoplasty/myringoplasty or canal wall down mastoidectomy.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Targeted history
2. Physical examination
3. Otoscopy
4. Binocular microscopy
5. Audiologic evaluation

Treatment/Management

1. Watchful waiting/observation
2. Education/information
3. Cerumenolytic agents
4. Ear canal irrigation
5. Manual removal other than irrigation (curette, probe, forceps, suction, hook)
6. Cotton-tip swabs (not recommended)
7. Ear candling (not recommended)

Prevention

1. Cerumenolytic agents
2. Hygiene
3. Education
4. Environmental controls

MAJOR OUTCOMES CONSIDERED

- Resolution or change in the signs and symptoms associated with cerumen impaction
- Complications/adverse events
- Cost
- Adherence to therapy
- Quality of life
- Return to work or activity
- Return physician visits
- Effect on comorbid conditions (e.g., sensorineural hearing loss, conductive hearing loss)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Several literature searches were performed through October 16, 2007. The initial MEDLINE search using "cerumen" or "earwax" or "ear wax" or "ear secretions" in any field yielded 1219 potential articles:

1. *Clinical practice guidelines* were identified by limiting the MEDLINE search using "guideline" as a publication type or title word. Search of the National Guideline Clearinghouse (www.guideline.gov) identified three guidelines with

a topic of cerumen or earwax. After eliminating articles that did not have cerumen impaction as the primary focus, no guidelines met quality criteria of being produced under the auspices of a medical association or organization and having an explicit method for ranking evidence and linking evidence to recommendations.

2. *Systematic reviews (meta-analysis)* were identified by limiting the MEDLINE search to 10 articles using a validated filter strategy for systematic reviews. Search of the Cochrane Library identified one relevant title. After eliminating articles that did not have cerumen impaction as the primary focus, five systematic reviews met quality criteria of having explicit criteria for conducting the literature search and selecting source articles for inclusion or exclusion.
3. *Randomized controlled trials* were identified by search of the Cochrane Controlled Trials Register, which identified 33 trials with "cerumen" or "earwax" or "ear wax" in any field.
4. *Original research studies* were identified by limiting the MEDLINE search to articles on humans published in English since 1966. The resulting data set of 796 articles yielded 177 randomized controlled trials, 78 reviews, 10 systematic reviews, three guidelines, and 538 other studies. The literature was further narrowed using the standard literature review process including removal of: topics without sufficient evidence; nonoriginal research; letters; commentaries; narrative reviews; nonclinical research; case reports; or uncontrolled case series.

Results of all literature searches were distributed to guideline panel members at the first meeting, including electronic listings with abstracts (if available) of the searches for randomized trials, systematic reviews, and other studies. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through December 14, 2007.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Quality for Grades of Evidence

Grade A: Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Expert opinion, case reports, reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized, and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in "Ratings Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. The multidisciplinary guideline development panel was chosen to represent the fields of audiology, family medicine, geriatrics, internal medicine, nursing, otolaryngology– head and neck surgery, and pediatrics.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the nine months devoted to guideline development ending in June 2008, the group met twice, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.

An independent review group used the Guideline Implementability Appraisal and Extractor (GEM-COGS) to appraise adherence of the draft guideline to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in 2008 and modified an advanced draft of the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits, in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits, in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians should also generally follow a recommendation, but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (Grade D)* or that well-done studies (Grade A, B, or C)* show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No Recommendation: No recommendation means there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

* Refer to "Rating Scheme for the Strength of the Evidence" field above for the definitions of evidence grades.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final draft practice guideline underwent extensive external peer review. Comments were compiled and reviewed by the group chairpersons.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grades (**A-D, X**) and evidence-based statements (**Strong Recommendation, Recommendation, Option, and No Recommendation**) are defined at the end of the "Major Recommendations" field.

Statement 1a. Diagnosis of Cerumen Impaction

Clinicians should diagnose cerumen impaction when an accumulation of cerumen 1) is associated with symptoms, or 2) prevents needed assessment of the ear, or 3) both.

Recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.

Evidence Profile:

- Aggregate evidence quality: **Grade B**, diagnostic studies with minor limitations regarding impact of cerumen on hearing and visualizations and **Grade C** with respect to signs and symptoms associated with cerumen impaction
- Benefit: Identify individuals with cerumen impaction who require intervention including those with otologic symptoms and those who require diagnostic assessment (raise awareness of the consequences of cerumen impaction—e.g., cerumen impaction prevents caloric stimulation during electronystagmography)
- Harm: Overdiagnosis of cerumen impaction based on symptoms as a criterion resulting in failure to identify another cause of the symptoms
- Cost: no additional cost
- Benefits-harm assessment: preponderance of benefits over harm
- Value judgments: emphasis on clinical symptoms and signs for initial diagnosis; importance of avoiding unnecessary diagnostic tests; consensus on using the term "cerumen impaction" to imply cerumen that requires treatment
- Role of patient preferences: not applicable
- Policy level: **recommendation**

Statement 1b. Modifying Factors

Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management such as one or more of the following: non-intact tympanic membrane, ear canal stenosis, exostoses, diabetes mellitus, immunocompromised state, or anticoagulant therapy.

Recommendation based on observational studies with a preponderance of benefit over harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C and D**, observational studies
- Benefit: Reduce complications
- Harm: No harm
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: consensus that identifying modifying factors and modifying management will improve outcomes
- Policy level: **recommendation**

Statement 2. Observation of Nonimpacted Cerumen

Clinicians may observe patients with non-impacted cerumen that is asymptomatic and does not prevent the clinician from adequately assessing the patient.

Option based on randomized controlled trials with heterogeneity in diagnostic criteria and illness severity, and a relative balance of benefit and harm.

Evidence Profile:

- Aggregate evidence quality: **Grade D**, one observational study, expert opinion, and first principles
- Benefit: avoid unnecessary treatment
- Harm: potential progression to impaction
- Cost: none
- Benefits-harm assessment: relative balance of harm vs benefit for nonimpacted cerumen
- Medical reasons for exceptions to this statement include, but are not limited to, history of recurrent cerumen impaction
- Value judgments: minimize unnecessary treatment, increase recognition of the benefits of cerumen
- Role of patient preferences: substantial role for shared decision making
- Policy level: **option**

Statement 3a. Need for Intervention

Clinicians should treat cerumen impaction that causes symptoms expressed by the patient or prevents clinical examination when warranted.

Strong recommendation based on randomized controlled trials with heterogeneity with a preponderance of benefit over harm.

Evidence Profile:

- Aggregate evidence quality: **Grade B**, randomized controlled trials with heterogeneity
- Benefit: improved hearing and symptom relief compared with no treatment
- Harm: potential complications related to treatment
- Benefits-harm assessment: preponderance of benefit over harm
- Role of patient preferences: some role for shared decision making
- Policy level: **strong recommendation**

Statement 3b. Need for Intervention in Special Populations

Clinicians may distinguish and promptly evaluate the need for intervention in the patient who may not be able to express symptoms but presents with cerumen obstructing the ear canal.

Option based on cohort and observational studies with a balance of benefit and harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C**, cohort and observational studies
- Benefit: improved hearing and functional health status
- Harm: potential overtreatment of cerumen that is asymptomatic
- Cost: evaluation and treatment costs; substantial administrative burden in settings with a high prevalence of cognitively impaired individuals, such as nursing homes and institutional facilities
- Benefits-harm assessment: balance of benefit and harm
- Value judgments: importance of identifying and treating cerumen impaction in special populations
- Role of patient preferences: there is no role for patient preferences when the patient is unable to express preferences
- Policy level: **option**

Statement 4. Hearing Aid Use

The clinician should examine patients with hearing aids for the presence of cerumen impaction during a healthcare encounter.

Recommendation based on cohort and observational studies with a preponderance of benefit over harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C**, observational studies
- Benefit: prevent hearing aid dysfunction and associated repair costs
- Harm: overtreatment of asymptomatic cerumen
- Benefits-harm assessment: preponderance of benefit over harm
- Role of patient preferences: some role for shared decision making
- Policy level: **recommendation**

Statement 5a. Therapeutic Interventions

Clinicians should treat the patient with cerumen impaction with an appropriate intervention, which may include one or more of the following: cerumenolytic agents, irrigation, or manual removal other than irrigation.

Recommendation based on randomized controlled trials and observational studies with a preponderance of benefit over harm.

- Aggregate evidence quality: **Grade B and C**, randomized controlled trials with limitations and cohort studies

- Benefit: improved cerumen removal by using effective therapies and to avoid harm from ineffective or untested therapies
- Harm: specific adverse effects related to treatments used
- Cost: no cost associated with the decision to use appropriate therapy
- Benefits-harm assessment: preponderance of benefit over harm
- Value judgments: Therapy should be effective and minimize harm
- Role of patient preferences: Selection of office vs appropriate home treatment
- Policy level: **recommendation**

Statement 5b. Cerumenolytic Agents

Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction.

Option based on limited randomized trials with a balance of benefit and harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C**, individual treatment arms of randomized trials showing beneficial outcomes, one randomized controlled trial suggesting better outcomes over no treatment
- Benefit: safe and effective removal of impacted cerumen
- Harm: potential external otitis, allergic reactions, and otalgia
- Cost: cost of cerumenolytic agents other than water or saline solution, cost of procedure if performed in an office setting
- Benefits-harm assessment: balance of benefit and harm
- Medical reasons for exceptions to this statement include, but are not limited to, persons with a history of allergic reactions to any component, persons with infection of the ear canal or active dermatitis, and persons with a nonintact tympanic membrane
- Value judgments: the panel values cost control and safety in view of limited data on absolute and comparative efficacy
- Role of patient preferences: substantial role for shared decision making
- Policy level: **option**

Statement 5c. Irrigation

Clinicians may use irrigation in the management of cerumen impaction.

Option based on randomized controlled trials with heterogeneity and with a balance of benefit and harm.

Evidence Profile:

- Aggregate evidence quality: **Grade B**, one randomized controlled trial verifying absolute efficacy but multiple treatment arms of comparative studies verifying benefit over cerumenolytic alone
- Benefit: improved outcome of irrigation vs cerumenolytic alone
- Harm: external otitis, vertigo, tympanic membrane perforation, otalgia, temporal bone osteomyelitis
- Cost: cost of supplies and procedure

- Benefits-harm assessment: balance of benefit and harm
- Value judgments: panel enthusiasm was tempered by the lack of appropriate head-to-head trials comparing irrigation to manual removal or cerumenolytics
- Medical reasons for exceptions to this statement include, but are not limited to, persons with open tympanic membrane, active dermatitis or infection, or anatomic abnormalities of the ear canal
- Role of patient preferences: role for shared decision making
- Policy level: **option**

Statement 5d. Manual Removal

Clinicians may use manual removal other than irrigation in the management of cerumen impaction.

Option based on case series and expert opinion with a balance of benefit and harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C and D**, observational case series and expert opinion
- Benefit: removal of cerumen impaction under direct visualization
- Harm: bleeding, laceration, tympanic membrane perforation, otalgia
- Cost: procedural cost; equipment cost
- Benefits-harm assessment: balance of benefit and harm
- Value judgments: Recommendation acknowledges widespread practice of manual removal but this is tempered by the relative absence of evidence
- Role of patient preferences: role for shared decision making
- Policy level: **option**

Statement 6. Outcomes Assessment

Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, alternative diagnoses should be considered.

Recommendation based on randomized controlled trials with limitations supporting a failure of clearance of cerumen in some cases and randomized controlled trials with limitations and a preponderance of benefit over harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C**; observation in treatment arms of several randomized trials shows that retreatment is sometimes necessary and can be effective; first principles support evaluation for efficacy after treatment
- Benefit: detect complications, detect misdiagnosis, institute effective therapy
- Harm: see sections on individual treatments
- Cost: cost of additional treatment or evaluation
- Benefits-harm assessment: preponderance of benefit over harm

- Value judgments: importance of clinician assessment after treatment; avoid misdiagnosis
- Role of patient preferences: limited
- Policy level: **recommendation**

Statement 7. Prevention

Clinicians may educate/counsel patients with cerumen impaction/excessive cerumen regarding control measures.

Option based on survey and comparative studies with unclear balance of benefit vs harm.

Evidence Profile:

- Aggregate evidence quality: **Grade C**; observational studies and expert opinion
- Benefit: prevent development of cerumen impaction
- Harm: side effects of preventive measures
- Cost: cost of control measures, minimal
- Benefits-harm assessment: balance benefit over harm
- Value judgments: importance of prevention in managing patients with cerumen impaction
- Role of patient preferences: substantial opportunities for shared decision making
- Policy level: **option**

Definitions:

Guideline Definitions for Evidence-Based Statements

Strong Recommendation: A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits, in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication*: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation: A recommendation means the benefits exceed the harms (or that the harms exceed the benefits, in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication*: Clinicians should also generally follow a recommendation, but should remain alert to new information and sensitive to patient preferences.

Option: An option means that either the quality of evidence that exists is suspect (Grade D) or that well-done studies (Grade A, B, or C) show little clear advantage to one approach versus another. *Implication*: Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No Recommendation: No recommendation means there is both a lack of pertinent evidence (Grade D) and an unclear balance between benefits and harms. *Implication*: Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Evidence Quality for Grades of Evidence

Grade A: Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline's target population

Grade B: Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case-control and cohort design)

Grade D: Expert opinion, case reports, reasoning from first principles (bench research or animal studies)

Grade X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations contained in the practice guideline are based on the best available published data through October 2007. Where data are lacking, a combination of clinical experience and expert consensus was used. The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved diagnostic accuracy for cerumen impaction
- Appropriate intervention in patients with cerumen impaction
- Appropriate evaluation and intervention in special populations
- Appropriate therapeutic options with outcomes assessment

- Improved counseling and education for prevention of cerumen impaction

Note: For benefits of the specific interventions considered in the guideline, see the "Major Recommendations" field.

POTENTIAL HARMS

For harms associated with specific interventions considered in the guideline, see the "Major Recommendations" field.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Cerumenex and Murine are used only in combination with irrigation because leaving the ear drops in the ear canal for more than 30 minutes is contraindicated.
- Studies evaluating cerumenolytics exclude patients with otitis externa; therefore, cerumenolytics should be avoided in patients with active infections of the ear canal.
- Ear syringing should not be performed in individuals who have had ear surgery or who have a nonintact tympanic membrane.
- Aural irrigation should be avoided in individuals with anatomic abnormalities of the canal (congenital malformations, osteomas, exostosis, scar tissue, etc) that might trap water in the external auditory canal after irrigation.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This clinical practice guideline is not intended as a sole source of guidance in managing cerumen impaction. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. It is not intended to replace clinical judgment or establish a protocol for all individuals with this condition, and may not provide the only appropriate approach to diagnosing and managing this problem.
- Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less-frequent variation in practice is expected for a "strong recommendation" than might be expected with a "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates, and they do not and should not purport to be a legal standard of care. The responsible physician, in light of all the

circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), Inc. emphasizes that these clinical guidelines should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. A full-text version of the guideline will also be accessible free of charge for a limited time at the www.entnet.org, the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) website. Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

An anticipated barrier to diagnosis is distinguishing modifying factors for cerumen impaction in a busy clinical setting, which may be assisted by a laminated teaching card or visual aid summarizing important factors that modify management.

Anticipated barriers to using an "observation option" for nonimpacted cerumen are reluctance of patients and clinicians to consider observing cerumen, and misinterpretation by clinicians and lay press of the statement regarding observation of nonimpacted cerumen as a "recommendation" instead of an "option." These barriers can be overcome with educational pamphlets and information sheets that outline the favorable natural history of nonimpacted cerumen, moderate incremental benefit of removal on clinical outcomes, and potential adverse effects of treatment.

Prompt evaluation of special populations may be hindered by the high prevalence of cerumen impaction in these populations and additional treatment time that may be necessary in busy practice settings. Information sheets outlining the high prevalence and the potential morbidity of cerumen impaction in these populations may help clinicians to become more aware of this issue.

Performance of irrigation and instrument removal other than irrigation, when appropriate, may be hindered by access to equipment and by procedural cost. Lastly, successfully achieving an understanding of the lack of efficacy and potential harms of ear candling, a popular alternative therapy, will require patient and clinician access to educational materials. Pamphlets may help in dispelling myths about comparative efficacy.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, Fayad J, Harlor AD Jr, Hirsch BE, Jones SS, Krouse HJ, Magit A, Nelson C, Stutz DR, Wetmore S. Clinical practice guideline: cerumen impaction. Otolaryngol Head Neck Surg 2008 Sep;139(3 Suppl 2):S1-21. [97 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Sep

GUIDELINE DEVELOPER(S)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Otolaryngology--Head and Neck Surgery Foundation

GUIDELINE COMMITTEE

American Academy of Otolaryngology--Head and Neck Surgery Guidelines Development Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Peter S. Roland, MD; Timothy L. Smith, MD, MPH; Seth R. Schwartz, MD, MPH; Richard M. Rosenfeld, MD, MPH; Bopanna Ballachanda, PhD; Jerry M. Earll, MD; Jose Fayad, MD; Allen D. Harlor Jr, MD; Barry E. Hirsch, MD; Stacie S. Jones, MPH; Helene J. Krouse, PhD; Anthony Magit, MD; Carrie Nelson, MD, MS; David R. Stutz, MD; Stephen Wetmore, MD, MBA

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past five years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they: 1) reminded the panel of potential conflicts before any related discussion, 2) recused themselves from a related discussion if asked by the panel, and 3) agreed not to discuss any aspect of the guideline with industry before publication. Lastly, panelists were reminded that conflicts of interest extend beyond financial relationships, and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Financial Disclosures

Peter S. Roland, Consultant: Alcon Labs, MedEl Corporation, Advanced Bionics, Cochlear Corporation; Speaker: Glaxo Smith Kline, Alcon Labs; Timothy L. Smith, Consultant: Acclarent and Sinexus; Research grant from NIH; Helene J. Krouse, Consultant: Krames Communication; Speaker: Alcon; Grant support: Schering-Plough; Speakers bureau: Sanofi- Aventis; Former stockholder: Alcon.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of the Otolaryngology - Head and Neck Surgery journal.

Print copies: Available from Peter S. Roland, MD, Professor and Chairman, UT-Southwestern, Department of Otolaryngology, 5323 Harry Hines Blvd, Dallas, TX 75390; E-mail address: peter.roland@utsouthwestern.edu.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on March 27, 2009. The information was verified by the guideline developer on March 31, 2009.

COPYRIGHT STATEMENT

1. If any part of the material to be used (for example, figures) has appeared in our publication with credit or acknowledgement to another source, permission must also be sought from that source. If such permission is not obtained then that material may not be included in your publication/copies.
2. Suitable acknowledgement to the source must be made, either as a footnote or in a reference list at the end of your publication, as follows:

   "Reprinted from Publication title, Vol number, Author(s), Title of article, Pages No., Copyright (Year), with permission from American Academy of Otolaryngology – Head and Neck Surgery Foundation, Inc."

3. Reproduction of this material is confined to the purpose for which permission is hereby given.
4. This permission is granted for non-exclusive world **English** rights only. For other languages please reapply separately for each one required.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Copyright/Permission Requests

Date Modified: 4/20/2009


DEPARTMENT OF HEALTH & HUMAN SERVICES • USA